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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,117	10/31/2003	William J. Bertrand	M190.247.101 / P0011522.0	8914

7590 12/08/2010

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EXAMINER	
DORNA, CARRIE R	
ART UNIT	**PAPER NUMBER**
3735	

MAIL DATE	DELIVERY MODE
12/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,117	BERTRAND ET AL.	
	Examiner	Art Unit	
	Carrie Dorna	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 18-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 September 2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 8, 10-13, and 15-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2002/0022793 (Bertrand et al.) in view of U.S. Patent No. 6,305,381 (Weijand et al.).

Regarding **claim 8**, Bertrand et al. teaches an electronic magnetic-based indicator tool comprising: a housing (*Figure 10, indicator central body,* 60) having a connection and removable mounting to a locator tool (*Figure 4, locator tool,* 26) (Indicator central body of the indicator tool is placed within the tube of the locator tool, [0059]; removable, [0065]); a compass module (*Figure 12, compass,* 62) carried by the housing (60) for measuring an orientation of sensed magnetic fields ([0053]; [0056]; [0060]); and a locator tool interface (*Figure 9, index,* 88) carried by the housing (60) for communicating sensed magnetic field data to the user after

receiving magnetic data values from the compass module (62) ([0058]; [0060]); wherein the locator tool (26) necessarily receives background magnetic field data (When the indicator tool is in use as part of the locator tool, the compass necessarily detects ambient magnetic fields.), receives target magnetic field data when the indicator tool (*Figure 9, indicator tool,* 28) is connected to the locator tool (26) and is located above an implanted flow control device having a magnetic indicator device (*Figure 1, magnet,* 20) coupled to a valve (*Figure 1, valve,* 10) ([0010]; [0060]); determines an orientation of the magnetic indicator device (*Figures 3A-3E, magnet,* 20) based upon the background magnetic field data and the target magnetic field data ([0060]); and determines a setting for the valve (10) from the determined orientation of the magnetic indicator device (20) ([0060]). Bertrand et al. does not teach that the indicator tool comprises an electronic processor for electronically locating and determining the setting of the valve.

However, Weijand et al. teaches an electronic magnetic-based indicator tool (*Figures 1 and 4, array,* 3 and *location processor,* 2) comprising: a housing having an electric connection and removable mounting to a locator tool (*Figures 1 and 4, microprocessor,* 54) (col. 2, lines 44-47; col. 3, lines 17-19; col. 3, line 56-col. 4, line 13; see *Figures 1 and 4*; device necessarily has a housing containing the array and processor with an electrical connection therebetween that is "removable"); an electronic compass module (*Figures 1 and 4, antennas,* 30-32) carried by the housing for measuring an orientation of sensed magnetic fields (col. 3, lines 31-35 and lines 43-52); and a locator tool interface module (*Figure 4, switch,* 50, *amplifier,* 51, and *computer,* 53) carried by the housing for electronically communicating sensed magnetic field data to a processing module (*Figure 4,* data analysis programming of *microprocessor,* 54) in the locator

tool (54) for receiving magnetic data values from the electronic compass module (30-32) (col. 3, line 56-col. 4, line 13); wherein the processing module (programming, 54) necessarily receives and stores background magnetic field data (Ambient magnetic fields are necessarily detected by the array and processor if they are present.); receives target magnetic field data from the electronic compass module (30-32) when the indicator tool (2 and 3) is connected to the locator tool (54) and is located above an implanted device (*Figure 1, medical device,* 4) having a magnetic indicator device (*Figures 1 and 4, implanted coil,* 22) (col. 2, lines 44-50; col. 3, lines 31-35 and lines 43-52); and electronically determines an orientation of the magnetic indicator device (22) based upon the background magnetic field data and the target magnetic field data (col. 3, lines 31-35 and lines 43-52). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the detection system of Bertrand et al. to electronically detect the location and orientation of the magnetic field emitted by the implanted medical device wherein magnetic fields are electronically sensed by the indicator tool and analyzed by a processor in the locator tool similar to the detection system of Weijand et al., because an electronic detection and processing system provides a noninvasive, automated mechanism which reduces the potential for human error in detecting the location and orientation of an implanted medical device.

Regarding **claim 10**, Bertrand et al. in view of Weijand et al. teaches all the limitations of claim 8. Bertrand et al. teaches that the indicator tool (*Figure 10, indicator tool,* 28) further comprises a mechanical key device (*Figure 10, ridge,* 70) about its housing for orientating the indicator tool (28) into a desired position relative to a locator tool (*Figure 4, locator tool,* 26)

placed in a desired orientation relative to the implanted flow control device ([0054]; [0070]-[0071]).

Regarding **claim 11**, Bertrand et al. in view of Weijand et al. teaches all the limitations of claim 8. Bertrand et al. teaches that the indicator tool (*Figure 10, indicator tool,* 28) corresponds to a handheld device ([0014]).

Regarding **claim 12**, Bertrand et al. in view of Weijand et al. teaches all the limitations of claim 11. Bertrand et al. and Weijand et al. teach that the handheld device includes a removable battery (Weijand et al., *Figure 1, battery,* 21) (The battery is necessarily able to be removed from the remainder of the device, Weijand et al., col. 64-67).

Regarding **claim 13**, Bertrand et al. teaches an electronic magnetic-based indicator tool comprising: an indicator tool housing (*Figure 10, indicator central body,* 60) configured for removable assembly to a housing of a locator tool (*Figure 4, locator tool,* 26) (Indicator central body of the indicator tool is placed within the tube of the locator tool, [0059]); a compass module (*Figure 12, compass,* 62) with the indicator tool housing (60) for measuring an orientation of sensed magnetic fields ([0053]; [0060]); and a locator tool interface (*Figure 9, index,* 88) communicating sensed magnetic field data to the user after receiving magnetic data values from the compass module (*compass,* 62) ([0058]; [0060]); wherein the indicator tool (*Figure 9, indicator tool,* 28) necessarily receives background magnetic field data from the compass module (62) independent of assembly of the indicator tool housing (60) to the housing of the locator tool (28) (When the compass 62 is placed in operating position in the indicator tool housing 60, regardless of whether or not the indicator tool housing is placed in the locator tool 28, the compass necessarily detects ambient magnetic fields.); receives target magnetic field data

when the indicator tool (28) is assembled to the housing of the locator tool (26) and the indicator tool (28) is located above an implanted flow control device having a magnetic indicator device (*Figure 1, magnet,* 20) coupled to a valve (*Figure 1, valve,* 10) ([0010]; [0060]); and determines a setting for the valve (*valve,* 10) within the implanted flow control device based upon the background magnetic field data and the target magnetic field data ([0060]). Bertrand et al. does not teach that the indicator tool comprises an electronic processor.

However, Weijand et al. teaches an electronic magnetic-based indicator tool (*Figures 1 and 4, array,* 3 and *location processor,* 2) comprising: a housing having an electric connection and removable mounting to a locator tool (*Figures 1 and 4, microprocessor,* 54) (col. 2, lines 44-47; col. 3, lines 17-19; col. 3, line 56-col. 4, line 13; see *Figures 1 and 4*; device necessarily has a housing containing the array and processor with an electrical connection therebetween that is "removable"); an electronic compass module (*Figures 1 and 4, antennas,* 30-32) carried by the housing for measuring an orientation of sensed magnetic fields (col. 3, lines 31-35 and lines 43-52); and a locator tool interface module (*Figure 4, switch,* 50, *amplifier,* 51, and *computer,* 53) carried by the housing for electronically communicating sensed magnetic field data to a processing module (*Figure 4,* data analysis programming of *microprocessor,* 54) in the locator tool (54) for receiving magnetic data values from the electronic compass module (30-32) (col. 3, line 56-col. 4, line 13); wherein the processing module (programming, 54) necessarily receives and stores background magnetic field data (Ambient magnetic fields are necessarily detected by the array and processor if they are present.); receives target magnetic field data from the electronic compass module (30-32) when the indicator tool (2 and 3) is connected to the locator tool (54) and is located above an implanted device (*Figure 1, medical device,* 4) having a

magnetic indicator device (*Figures 1 and 4, implanted coil,* 22) (col. 2, lines 44-50; col. 3, lines 31-35 and lines 43-52); and electronically determines an orientation of the magnetic indicator device (22) based upon the background magnetic field data and the target magnetic field data (col. 3, lines 31-35 and lines 43-52). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the detection system of Bertrand et al. to electronically detect the location and orientation of the magnetic field emitted by the implanted medical device wherein magnetic fields are electronically sensed by the indicator tool and analyzed by a processor in the locator tool similar to the detection system of Weijand et al., because an electronic detection and processing system provides a noninvasive, automated mechanism which reduces the potential for human error in detecting the location and orientation of an implanted medical device.

Regarding **claim 15**, see discussion for claim 10.

Regarding **claim 16**, see discussion for claim 11.

Regarding **claim 17**, see discussion for claim 12.

4. **Claims 9 and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2002/0022793 (Bertrand et al.) in view of U.S. Patent No. 6,305,381 (Weijand et al.) as applied to claims 8 or 13 above, and further in view of U.S. Patent No. 5,136,242 (Abraham-Fuchs).

Regarding **claims 9 and 14**, Bertrand et al. in view of Weijand et al. teaches all the limitations of claims 8 and 13 above. Bertrand et al. and Weijand et al. teach that the device necessarily detects background magnetic field data as well as target magnetic field data, but does

not teach that the background data is subtracted from the target data to determine the true location and orientation of the sensed magnetic fields in the implant.

However, Abraham-Fuchs teaches a device for detecting the magnetic field emanating from a source in a patient's body comprising a processing module (*Figure 1, computer,* 9) subtracts measured background magnetic field data from measured target magnetic data to determine the location of the true target magnetic data (col. 1, lines 43-53; col. 2, lines 14-20 and lines 35-38; col. 3, lines 17-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the processing module of Bertrand et al. and Weijand et al. to subtract the background magnetic field data from the target magnetic field data to localize the target as taught by Abraham-Fuchs, because subtracting background magnetic field data from target magnetic field data prevents a false localization of the target magnetic field (Abraham-Fuchs, col. 3, lines 17-20 and lines 47-48).

Response to Arguments

5. Applicant's arguments filed 24 September 2010 have been fully considered but they are not persuasive.

Applicant contends that Bertrand et al. in view of Weijand et al. does not teach the device as required in amended claim 8 because Bertrand et al. does not teach that the locator houses a processing module for determining an orientation of the magnetic indicator device and determining a setting for the valve. The Examiner does not find this argument to be persuasive as Applicant has not addressed the resulting combination of Bertrand et al. and Weijand et al. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must

be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Furthermore, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Considering the combination of Bertrand et al. and Weijand et al., one of ordinary skill in the art would recognize the benefit of electronically determining the position and orientation of an implanted valve by detecting electromagnetic fields emitted from the implant in an indicator tool, analyzing the detected signals in a processor of a locator tool to calculate the position and orientation, and determining the setting of the valve based upon that calculated position and orientation (see rejection of claims 8 and 13 above).

6. Applicant contends that Bertrand et al. in view of Weijand et al. does not teach the device as required in amended claim 13 because the combination of these references "necessarily incorporates an entirety of the antenna array 3 within the Bertrand indicator tool 28" (arguments, p. 13). Applicant further asserts that this bodily incorporation of Weijand et al. into Bertrand et al. would not result in a device having a target compass module in the indicator tool and a separate background compass module in the locator tool. The Examiner does not find these arguments to be persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a target compass module housed in the indicator tool that is separate from a background compass module housed in the locator tool) are not recited in the rejected claim(s). Although the

claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The broadest reasonable interpretation of claim 13 does not necessarily require that the target and background compass modules are physically separate and housed in physically separate locations of the device. Rather, it requires that a target compass module is housed at some location in the indicator tool housing, and a background compass module is housed at some location in the locator tool (which may also be within the indicator tool housing). Bertrand et al. teaches that the compass is housed within the indicator tool, which is housed within the locator tool. Therefore, the compass, which necessarily detects both target and background magnetic fields regardless of its assembly in the locator tool, is within both the indicator tool and the locator tool.

For these reasons above, the previous grounds of rejection citing Bertrand et al. in view of Weijand et al. have been maintained.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carrie Dorna whose telephone number is (571) 270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. D./
Examiner, Art Unit 3735